PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - <u>COMBINED LABEL AND PACKAGE LEAFLET</u>

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

POWDOX 125 mg/g Premix for medicated feeding stuff for pigs.

2. COMPOSITION

Each gram contains:

Active substance:

Doxycycline (hyclate)	125.0 mg
Equivalent to doxycycline hyclate	144.2 mg

Excipients:
Flour of hazelnut and almond shell

Brown yellowish powder

3. PACKAGE SIZE

Bag of 25 kg.

4. TARGET SPECIES

Pig (Pig for fattening)

5. INDICATIONS FOR USE

Treatment and metaphylaxis of pleuropneumonia caused by Actinobacillus pleuropneumoniae strains susceptible to doxycycline.
The presence of the disease in the herd should be established before use.

6. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any excipient.
Do not use in animals with hepatic dysfunction.

7. SPECIAL WARNINGS

Special warnings

The intake of medicated feed by animals can be altered as a consequence of illness. In case of insufficient intake of feed, animals should be treated parenterally.

<u>Special precautions for safe use in the target species:</u>
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to docycycline and may decrease the effectiveness of treatment with tetracyclines, due to the potential for crossresistance.
Consideration should be given to improvement of management practices on the farm. Particular attention should be paid to hygiene and ventilation, and management of pigs to avoid stress-related conditions.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.

Handle the veterinary medicinal product with care to avoid inhalation of dust particles and skin and eye contact during the incorporation of the premix into feed, taking into account the following specific recommendations:

- Take the necessary measures to avoid producing dust during the incorporation of the premix into feed.
- Personal protective equipment consisting of an appropriate dust mask (either a disposable half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143), impermeable gloves, overalls and approved safety goggles).
- Avoid skin and eye contact. In case of accidental exposure rinse immediately with plenty of water and if irritation occurs, seek medical attention.
- Do not smoke, eat or drink while handling the product.

In case of accidental ingestion or if you develop symptoms following exposure such as skin rash, you should seek medical advice immediately and show the package leaflet or the label to the physician.
Swelling of the face, lips or eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Special precautions for the protection of the environment:

Not applicable.

Pregnancy:
Laboratory studies in mice and rabbits have not produced any evidence of toxic effects. The safety of the veterinary medicinal product has not been established in pregnant sows, the use is not recommended during pregnancy.

Lactation:
The safety of the veterinary medicinal product has not been established in lactating sows, thus its use is not recommended during lactation.

Fertility:
Do not use in breeding animals.

Interactions with other medicinal products and other forms of interaction:
The absorption of doxycycline can be reduced in the presence of high amounts of Ca^{2+}, Fe^{3+}, Mg^{2+} or Al^{3+} in the diet. Do not administer together with antacids, kaolin and iron preparations and in conjunction with bactericidal antibiotics like beta-lactams.

Overdose:
Not described.

Special restrictions for use and special conditions for use:
To be administered by the veterinarian or under veterinarian supervision.

Major incompatibilities:
In the absence of compatibility studies, this veterinary product must not be mixed with other veterinary medicinal products.

8. ADVERSE EVENTS

Adverse events

Pig (Pig for fattening):

Rare (1 to 10 animals / 10,000 animals treated):
Allergic reactions and photosensitivity. Disorder of gastrointestinal flora*

* In prolonged treatments due to intestinal dysbiosis.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: <{national system details}>.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

In-feed use

The premix is administered directly mixed with feed according to the following dose:

10-12 mg of doxycycline/kg bodyweight/day, equivalent to 80-95 mg of the product/kg bodyweight/day.

Treatment should be continued for 8 days.

The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of doxycycline may need to be adjusted accordingly.
Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\text{mg of veterinary medicinal product per kg of feed} = \frac{\text{80 – 95 mg veterinary medicinal product /kg body weight day x average body weight (kg) of animals to be treated}}{\text{average daily feed intake (kg/animal)”}}$$

To ensure a correct dosage, body weight should be determined as accurately as possible.

The recommended incorporation rate into feed would be 2 kg of the veterinary medicinal product per tonne of feed.

The use of suitably calibrated measuring equipment is recommendedc.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

<Do not use {(Invented) name of veterinary medicinal product} if you notice {description of visible signs of deterioration}.>

11. WITHDRAWAL PERIODS

Withdrawal periods

Pigs for fattening:
Meat and offal: 5 days

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.
Do not store above 30 ºC.
Keep the bags tightly closed in order to protect from light and to avoid the introduction of contamination.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or <household waste>.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

EU/0/00/000/000

Pack sizes

Bag of 25 kg

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

<{DD/MM/YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder:
VETPHARMA ANIMAL HEALTH, S.L.
Les Corts, 23
08028 Barcelona
SPAIN

Manufacturer responsible for batch release:
LABORATORIOS KARIZOO, S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12
08140 – CALDES DE MONTBUI (Barcelona)
Spain
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

18. OTHER INFORMATION

<Other information>

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Shelf life of the veterinary medicinal product as packaged for sale: 2 yearsShelf life after first opening the immediate packaging: 2 months
Shelf life after incorporationinto meal or pelleted feed: 1 month

21. BATCH NUMBER

Lot {number}